UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/508,635 | 05/18/2000 | OLIVIER BALLEVRE | P00.0164 | 7617 |

29157 7590 06/12/2003

BELL, BOYD & LLOYD LLC
P. O. BOX 1135
CHICAGO, IL 60690-1135

| EXAMINER |
|---|
| LUKTON, DAVID |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1653 | |

DATE MAILED: 06/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/508,635 | BALLEVRE ET AL. | |
| | Examiner | Art Unit | |
| | David Lukton | 1653 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)[·] Responsive to communication(s) filed on *06 May 2003* .

2a)[·] This action is **FINAL**. 2b)[ ] This action is non-final.

3)[ ] Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)[·] Claim(s) *30,32-35 and 37-41* is/are pending in the application.

4a) Of the above claim(s) *33 and 34* is/are withdrawn from consideration.

5)[ ] Claim(s) _____ is/are allowed.

6)[·] Claim(s) *30,32,35 and 37-41* is/are rejected.

7)[ ] Claim(s) _____ is/are objected to.

8)[ ] Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)[ ] The specification is objected to by the Examiner.

10)[ ] The drawing(s) filed on _____ is/are: a)[ ] accepted or b)[ ] objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)[ ] The proposed drawing correction filed on _____ is: a)[ ] approved b)[ ] disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)[ ] The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)[ ] Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)[ ] All b)[ ] Some * c)[ ] None of:

1.[ ] Certified copies of the priority documents have been received.

2.[ ] Certified copies of the priority documents have been received in Application No. _____ .

3.[ ] Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)[ ] Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) [ ] The translation of the foreign language provisional application has been received.

15)[ ] Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) [ ] Notice of References Cited (PTO-892)
2) [ ] Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) [x] Information Disclosure Statement(s) (PTO-1449) Paper No(s) *25* .
4) [ ] Interview Summary (PTO-413) Paper No(s). _____ .
5) [ ] Notice of Informal Patent Application (PTO-152)
6) [ ] Other: .

Pursuant to the response filed 5/6/03 (paper No. 24), no claim has been added, amended, or cancelled. Claims 30, 32-35 and 37-41 remain pending. Claims 33-34 remain withdrawn from consideration; claims 30, 32, 35 and 37-41 are examined in this Office action.

Applicants arguments filed 5/6/03 have been considered and found not persuasive.

*

The following is a quotation of the first paragraph of 35 U.S.C. §112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 30, 32, 35 and 37-41 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification fails to teach a skilled physiologist how to use protein hydrolyzates and amino acids to promote "recovery" of an organ. As stated in *Ex parte Forman* (230 USPQ 546, 1986) and *In re Wands* (8 USPQ2d 1400, Fed. Cir., 1988), the factors to consider in evaluating the need (or absence of need) for "undue experimentation" are the following: quantity of experimentation necessary, amount of direction or guidance presented, presence

or absence of working examples, nature of the invention, state of the prior art, relative skill of those in that art, predictability or unpredictability of the art, and breadth of the claims.

As for the "nature of the invention", it is asserted in the specification (page 8, line 17+) that the disclosed protein hydrolyzates can be used to repair damage to the intestine. Also asserted (page 8, line 20+) is that the disclosed protein hydrolyzates can be used to treat Crohn's disease, diarrhea, colitis or sepsis, and further, that the disclosed protein hydrolyzates can be used to reverse damage to gut epithelial tissue that has resulted from a surgical procedure, or from any other cause. Though not specifically stated, the implication is that various diseases such as hepatitis, cirrhosis of the liver, and kidney infection can be successfully treated. Such diseases cause damage to organ tissue, and if the claimed method is to be effective, the protein hydrolyzates must be effective not only to accelerate wound healing, but overcome the pathological basis of the organ damage.

As for the "working examples", the specification discloses results which are consistent with the conclusion that if one administers a mixture of all 20 genetically encoded amino acids to a mammal, the relative weights of the stomach, intestine, duodenum jejunum, liver, gastrocnemius, soleus, and extensor will vary slightly if the ratio of amino acids is altered. This assertion is somewhat suspect, since no statistical analysis has been presented. For example, in the case of the duodenum, the standard deviation would not have to be high at all in order to justify the conclusion that the results are not statistically significant. Without

further information as to the variability in the data (that is presented on page 17), it is not particularly meaningful. The results are also not meaningful, since the amount of lipids and minerals (see page 14) were varied simultaneously with the amino acid composition. Furthermore, the total amount of amino acids varies from from feed mixture to the next. Thus, even if it turns out that the results on page 17 are statistically significant, it has not been determined the extent to which, or even whether, the observed changes in organ weights were the result of varying the amino acid composition, rather than the lipids and minerals. It may be the case that the changes in organ weights were due to changes in the total amount of amino acids administered, rather than variations in the amino acid content. Or maybe the changes in organ weights were due to changes in differential metabolism of the peptide fragments which were produced by the different hydrolysis methods (hydrolyzate 1, hydrolyzate 2 or hydrolyzate 3). Thus, in the disclosed experiments (specification) several different variables have been altered simultaneously, and it is impossible to determine the effects of any one of them taken alone. Furthermore, there is no control experiment. It has not been stated what the results are supposed to be relative to. If the feed compositions (feed 1 - feed 5) were given to rats which were already exhibiting a positive nitrogen balance, would there be any effect at all of the different feeds? Even if it turns out that the results on page 17 are statistically significant, and if could be determined what the cause (among the numerous variables) of the variance in organ weights might be,

the results are still not meaningful with respect to the claimed invention. The claimed invention is not drawn to a method of randomly altering the weights of selected organs. And even if the claims were drawn e.g., to a method of increasing the weight of the stomach, it is not at all clear how one would proceed. It may be true that if one uses, e.g., feed #5 rather than feed #1, one will obtain a slightly higher weight of the stomach. If it were to turn out that this difference is due to the amino acid content, rather than to the lipids and minerals (or one of the other variables), it would still not be evident how one would translate the results of feed #5 *versus* feed #1 into a general method of increasing stomach weight. It is not apparent which amino acids are necessary, or which are sufficient; it is not made clear wat degree of hydrolysis will produce the intended results, and which will not. And even if it were true that the specification taught the skilled artisan how to increase the weight of specific organs, there is no teaching as to how that teaching would translate into a showing of enablement for the claimed invention, which is that of using protein hydrolyzates and amino acids to promote "recovery" of an organ.

The results of a second experiment are presented on pages 21-24. What is shown here is that the rate of protein synthesis varies somewhat depending on which of the five feeds is used. The shortcomings of the experimental results described on page 17 apply here as well. First, the results are not statistically significant in the absence of further information as to the variability that is observed from one experiment to the next (for a given

feed composition). Second, there are several different variables (with respect to the feed composition itself) which are altered simultaneously. And third, even if there were a clear assertion as to the specific variable that is supposed to correlate with the increased protein synthesis, and even if there were an experimental basis for such an assertion, this would have little relevance to the claimed invention, which is that of using protein hydrolyzates and amino acids to promote "recovery" of an organ. The specification has presented no evidence that any such correlation exists between rate of protein synthesis, and recovery of an organ from wounding, physical trauma, or damage from an inflammatory condition. The reality is that one cannot "predict" such "recovery" based on rates of protein synthesis.

The following references discusses the issue of statistical analysis, and more importantly the issue of artifacts or invalid conclusions that can be drawn from an inadequate experimental design, or flawed assumption:

Ludbrook (*Clinical and Experimental Pharmacology and Physiology* **28** (5-6) 488-92, 2001)

Bryant (*Pediatric Allergy and Immunology* 9 (3) 108-15, 1998)

Bezeau (*Journal of Clinical and Experimental Neuropsychology* 23 (3) 399-406, 2001)

Bolton (*Journal of Clinical Pharmacology* 38 (5) 408-12, 1998)

Willenheimer (*Progress in Cardiovascular Diseases* 44 (3) 155-67, 2001)

Chung (*Plastic and Reconstructive Surgery* 109 (1) 1-6, 2002)

Atkinson (*Chronobiology International* 18 (6) 1041-53, 2001).

While several experiments have been conducted, there is no apparent relationship between the results of those experiments, and the claimed invention. The claimed invention encompasses repair of damage to the intestines, treatment of Crohn's disease, treatment of diarrhea, treatment of colitis or sepsis, treatment of hepatitis, treatment of cirrhosis of the liver, and kidney infection, as well as reversal of damage to gut epithelial tissue. There is no evidence that increasing DNA synthesis or even increasing organ weight engenders a method of promoting wound healing, or of successfully treating a patient whose organs have been damaged by disease, surgery or trauma. "Undue experimentation" would be required to practice the claimed invention.

In response to the foregoing, it is argued (response, 5/6/03), that adequate direction is provided to enable the skilled artisan to **prepare** the "dietary protein" mixture to which the claims are drawn, but this does not address the issue raised in the previous Office action, which was how to "use" the "dietary protein" mixture.

It is also argued (page 3, paper No. 24) that a protein hydrolyzate having a degree of hydrolysis of 17% or greater and containing free amino acids increased the weight of the intestine to a greater extent than other feed compositions. The page number where this is disclosed is not stated, but on page 23 it is stated that protein synthesis is increased more in feeds 3 -5 than in feeds 1 and 2. There is no indication of the extent of variability of

the data, and it cannot be determined whether the difference in protein synthesis between feeds 3-5 and feeds 1-2 is statistically significant. If the results are statistically significant, then it can be concluded that for an animal which is permitted only a limited nitrogen intake, protein synthesis is greater when the degree of hydrolysis is e.g., 30% as compared with e.g., 17%. However, the claims are not drawn to a method of increasing protein synthesis. In addition, there is no lower limit on the degree of hydrolysis in most of the claims (as long as the degree of hydrolysis is finite). Administration of hydrolyzed proteins to an animal that is already exhibiting a positive nitrogen balance will produce little change in organ weights; and there is no indication that the hydrolyzed proteins can promote "recovery" to the extent that Crohn's disease, diarrhea, colitis or sepsis are successfully treated.

*

Claims 30, 32, 35 and 37-41 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- The claims are drawn to a method of promoting "recovery" of an organ. From what is the organ recovering? Is it a wound, physical trauma, or a disease? In response, it is argued (response filed 5/6/03) that the specification provides a brief description of what may be encompassed. However, it remains unclear the full extent of what is encompassed. It is suggested that the claim be amended to make clear what the mammal is recovering from.

- Claim 30 recites the following:

  "...selecting a dietary protein selected from ... a protein hydrolysate... [and]...amino acids...".

  However, a "dietary protein" is not *per se* an amino acid. In the response filed 5/6/03, it is argued that there is antecedent basis for this assertion in the specification; however, this does not resolve the issue.

*

The following is a quotation of 35 USC §103 which forms the basis for all obviousness rejections set forth in the Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.
>
> This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claims 30, 32, 35 and 37-41 are rejected under 35 U.S.C. §103 as being unpatentable over Ballard (USP 5,679,771) in view of Duguay (*Journal of Biological Chemistry* **270** (29) 17566-74, 1995).

As indicated previously, Ballard discloses that IGF-1 increases the weight of the gut (including intestines and jejunum) and improves gut function, and accelerates healing of damaged gut tissue. Duguay discloses that IGF-1 is a "protein hydrolyzate".

In the response filed 5/6/03, it is argued that (a) since IGF-1 is a hormone, it cannot be a "dietary protein", since a "dietary protein" must have a "nutritive purpose", and (b) it would be "nonsensical" or "dangerous" to use IGF-1 in a "dietary application". It is further implied, though not clearly stated, that IGF-1 is not "proteinogenic".

With regard to the last point, the physiologist of ordinary skill would expect that IGF-1 is "proteinogenic". The physiologist of ordinary skill would expect the IGF-1 to be hydrolyzed to amino acids by proteolytic enzymes, and the resulting amino acids incorporated into proteins during the normal course of anabolism . First, the IGF-1 is vulnerable to proteases (e.g., trypsin, chymotrypsin, elastase, pepsin, carboxypeptidase, and dipeptidase) that are present in the stomach and the small intestine. These proteases do not discriminate between pharmacologically active peptides, and those that are inactive. The intact IGF-1 that survives long enough to be conveyed into the bloodstream is next broken down over a period of hours by serum and liver enzymes. The peptides and amino acids that are generated by either of these processes are no less proteinogenic than are the peptides and amino acids which are the subject of the claimed invention.

As indicated above, it has been argued (response filed 5/6/03) that if a peptide acts as

a hormone, the peptide cannot be part of a diet. As recited in the Stedman's Medical Dictionary 27th Edition, the term "diet" is defined as follows:

1) Food and drink in general;

2) A prescribed course of eating and drinking in which the amount and kind of food, as well as the times at which it is to be taken, are regulated for therapeutic purposes;

3) Reduction of caloric intake so as to lose weight;

4) To follow any prescribed or specific diet.

The term "food" is defined (in the same dictionary) as "that which is eaten to supply necessary nutritive elements". A corollary to the foregoing would be that the term "diet" would encompass the following:

*A prescribed course of orally ingesting a nutritive element for therapeutic purposes.*

It is not being argued by the examiner that the skilled artisan would come to believe (after considering Ballard '771) that 100% of the dry weight of a person's diet should consist of IGF-1, or even 10% of the dry weight of a person's diet. A nutritionist or physician of ordinary skill would have recognized that IGF-1 should be administered to a person who would benefit from the growth or recovery of an organ such as the stomach, intestine, duodenum, colon, jejunum or kidney, and that the amount would be such as to be therapeutically effective, but no more. A quantity of 100 - 1000 micrograms/kg is

suggested (col 4, line 14) by Ballard. Certainly, for a person afflicted with a gut disorder, or who is endeavoring to increase the weight of an organ, IGF-1 would qualify as a "nutritive element for therapeutic purposes" every bit as much as a purified protein hydrolyzate or amino acid. If a person were to ingest a tablet containing, e.g., 3 mg IGF-1 at each meal over the course of a day, the IGF-1 would certainly at least qualify as a "dietary supplement". As such, the IGF-1 is a "dietary protein". There is no evidence that adminstration of IGF-1 in a therapeutic dose would be "nonsensical" or "dangerous".

In addition to the foregoing, the claimed invention encompasses a method which is applicable not only to adult humans, but also to infants, and to animals. In administering the IGF-1 to an infant, where it might be impractical to use a tablet or pill as the delivery vehicle, the nutritionist or pediatric specialist would direct that the IGF-1 be added to the infant formula which contains other nutrients. As such, the vehicle containing the IGF-1 and the other nutrients would be one and the same; certainly for this application, the IGF-1 is a "dietary protein". In addition, as indicated, the claimed invention also encompasses administration to animals. This would include dogs, cats, and zoo animals. As a practical matter, the easiest way to administer a given compound to an animal is to mix it with the animal's food. When administered in this way, the IGF-1 is a "dietary protein".

Finally, there is another possibility for administration, and that is to feed the animal (e.g., a lion in a zoo) raw meat. The veterinarian of ordinary skill would recognize that IGF-1

is present in a variety of tissues (e.g., the liver) and as such would feed raw meat to an animal with the intent of administering IGF-1 (present in the tissues), in addition to other nutrients. Even some humans eat raw meat. For example, as disclosed in the Stedmans' Medical dictionary under "diet", the "Minot-Murphy diet" is described as the use of large amounts of **raw liver** or raw liver extract in the treatment of pernicious anemia. Certainly, by any definition, the IGF-1 that is present in the raw meat would qualify as a dietary protein.

Accordingly, it would have been obvious to the the nutritional or veterinary specialist of ordinary skill that administration of IGF-1 as part of a diet would promote the growth and recovery of organs. The rejection is maintained.

*

Claims 30, 32, 35 and 37, 38, 40, 41 are rejected under 35 U.S.C. §103 as being unpatentable over Ballard (USP 5,679,771) in view of Wunderlich (USP 5,614,219).

As indicated previously, Ballard discloses that IGF-1 increases the weight of the gut (including intestines and jejunum) and improves gut function, and accelerates healing of damaged gut tissue. Wunderlich discloses that biologically active peptides can be combined with gelatin (which is a protein hydrolyzate) to improve pharmacokinetic outcomes.

The primary traversal (response filed 5/6/03) is to repeat the arguments presented in the rejection over Ballard in view of Duguay. These arguments have been addressed by the

examiner above. In addition, even if it were true that, as a semantic matter, a protein that is pharmacologically active cannot be a "dietary protein", this ground of rejection would still be valid. That is because the gelatin contains a pharmacologically inactive protein hydrolyzate, which the instant specification discloses is the preferred example of a "dietary protein".

The rejection is maintained.

*

Claims 30, 32, 35 and 37-41 are rejected under 35 U.S.C. §103 as being unpatentable over Mukai, Kiyoshi (English Abstract of JP-3264525) or Mukai, Kiyoshi (JP-3264525).

Mukai discloses that glutamic acid-containing dipeptides (Glu-Ala, Gly-Gln, Glu-Gly) is effective to prevent catabolism of muscular proteins, and to accelerate synthesis of tissue proteins.

In the response filed 5/6/03, it is argued that the dipeptides disclosed in the reference would have to be chemically synthesized, and that this would add "costs and complexity" to the process. However, synthesis of dipeptides is very routine, the cost is low, and the exact structure and composition of the final product can be controlled precisely. Moreover, there is no mention of "costs" or "complexity" in any of the claims.

In the response filed 5/6/03, it is argued that a dipeptides cannot be obtained by hydrolyzing a larger peptide or protein. However, as indicated previously (Office action mailed

12/3/02), the dipeptides contained in the reference could be obtained by enzymatic or chemical hydrolysis of larger peptides. It is not being argued that this would be easier than chemical synthesis, only that the peptide chemist of ordinary skill would have recognized that the dipeptides could be obtained in this way. For example, if the dipeptide (e.g., Glu-Ala) is present at the C-terminus of a peptide, treatment of the peptide with an N-terminal exopeptidase would result in production of the target dipeptide ( together with several other amino acids). Similarly, the Edman degradation would yield the target dipeptide. As such, the dipeptides disclosed in the reference have the property of being protein hydrolyzates.

The rejection is maintained.

*

Claim 30 is rejected under 35 U.S.C. §103 as being unpatentable over Goldberg M. (*Horm Metab Res* **12** (3), 94-96, 1980).

As indicated previously, Goldberg discloses that administration of a protein hydrolyzate to rats resulted in an increase in DNA synthesis in liver cells.

In the response filed 5/6/03, it is argued that the disclosed blood plasma extract is not a dietary protein. However, the blood plasma extract disclosed in the reference was subjected to both hydrolysis and lyophilization. A protein chemist of ordinary skill would have expected hydrolyzed proteins to be the principle consituent of the composition

disclosed in the reference. There may be small amounts of other organic and inorganic compounds present as well. But none of the claims requires that the protein hydrolyzate be 100% pure. Claim 30 is drawn to a method which "comprises" administration of a protein hydrolyzate. Certainly, if medical specialist of ordinary skill administers a mixture which is 90% hydrolyzed protein, and administers the mixture for the purpose of promoting growth or recovery of an organ, he is meeting the requirements of the claims. The fact that other impurities may be present in the mixture does not negate the validity of this rejection.

The rejection is maintained.

*

Claim 30 is rejected under 35 U.S.C. §103 as being unpatentable over Mawatari (USP 5,580,903).

As indicated previously, Mawatari discloses that the amino acids alanine and glutamine are effective to regenerate liver.

In the response filed 5/6/03, it is argued that the amino acids alanine and glutamine are excluded from the scope of the claims. However, as stated in claim 30, the term "dietary protein" can include a single amino acid. It is also argued (response filed 5/6/03) that the claims require that when amino acids are administered, they must be present as part of a "balanced amino acid profile". However, there is no such limitation in any of the claims.

The rejection is maintained.

*

Claim 30 is rejected under 35 U.S.C. §103 as being unpatentable over Henningfield (USP 5,221,668).

Henningfield discloses (col 10, line 43+) that arginine promotes wound healing.

In the response filed 5/6/03, it is argued that the amino acid arginine is excluded from the scope of the claims. However, as stated in claim 30, the term "dietary protein" can include a single amino acid. It is also argued (response filed 5/6/03) that the claims require that when amino acids are administered, they must be present as part of a "balanced amino acid profile". However, there is no such limitation in any of the claims. The rejection is maintained.

Christopher S. F. Low

CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). The practice of automatically extending the shortened statutory period an additional month upon filing of a timely first response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED AND ANY EXTENSION FEE PURSUANT TO 37 CFR 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

*

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 703-308-3213. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached at (703) 308-2923. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

D. Lukton 6/11/03